

Livesey discloses a method for processing skin in a solution, freezing, and reconstituting the tissue with viable cells. Livesey does not teach or suggest Applicant's claimed invention at least because Livesey does not teach or suggest a devitalized matrix comprising an epithelial basement membrane and tunica propria derived from urinary bladder mucosa. Applicant respectfully submits that Livesey's skin, in contrast to Applicant's claimed invention, does not include a tunica propria. Accordingly, Livesey could not possibly teach or suggest Applicant's claimed invention and is an improper reference under 35 U.S.C. §102(b). Applicant respectfully requests withdrawal and reconsideration of the rejection of claims 1, 2, 6, and 8-10.

Amended independent claim 13 and depending claim 20 recite a composition comprising at least a portion of devitalized epithelial basement membrane and tunica propria of a mucosa delaminated from a mammalian epithelial tissue and shaped to conform to diseased, damaged, or defective cardiac tissue. Livesey fails to teach or suggest Applicant's claimed invention at least because Livesey does not teach a composition shaped to conform to diseased, damaged or defective cardiac tissue. Accordingly, Livesey is an improper reference under 35 U.S.C. §102(b). Applicant respectfully requests withdrawal and reconsideration of the rejection of claims 13 and 20.

Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Livesey combined with PCT Publication No. WO 98/25637 to Badylak (hereinafter "Badylak"), U.S. Patent No. 6,096,347 to Geddes et al. (hereinafter "Geddes"), and U.S. Patent No. 5,899,936 to Goldstein et al. (hereinafter "Goldstein"). Applicant respectfully traverses the rejections to the claims as amended.

Livesey is discussed above. None of Badylak, Geddes or Goldstein cure the deficiencies of Livesey. Applicants submit that Badylak teaches a composition made from liver including liver basement membrane. Goldstein discloses a bioprosthesis including a connective tissue matrix from a variety of tissues. Geddes discloses a submucosal tissue graft composition for cardiac valves. In contrast to Applicant's claimed invention, none of Badylak's liver matrix, Geddes' submucosal composition, or Goldstein's connective tissue matrix include a mammalian epithelial basement membrane and tunica propria. Accordingly, none of Livesey, Badylak, Goldstein, or Geddes, alone or combined, teach or

suggest Applicant's claimed invention. Applicant respectfully submits that the rejection of claims 1, 11, and 13, and depending claims 2-10, 12, and 14-20 under 35 U.S.C. §103(a) is improper and respectfully requests reconsideration and withdrawal of the rejection.

Information Disclosure Statement

Enclosed herewith is a fourth Supplemental Information Disclosure, PTO-1449 Form and copies of the references.

Related Pending Application

Applicant has filed an additional application, U.S. 09/691,345, related to the instant application claiming benefit of provisional application 60/171,733.

CONCLUSION

Applicant respectfully requests allowance of claims 1-29 in due course. If the Examiner believes that a telephonic interview would expedite prosecution of the instant application, the Examiner is invited to contact the undersigned at (617) 248-7044.

Respectfully submitted,

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MARKED COPY OF THE AMENDED CLAIMS

1. A [devitalized] matrix, comprising:

a devitalized mammalian epithelial basement membrane and tunica propria immediately subjacent to said basement membrane derived from the urinary bladder mucosa wherein said matrix induces restoration of [diseased, defective, or missing] cardiac tissue when placed in contact with [said] diseased, defective, or [missing]damaged cardiac tissue.

2. The [devitalized] matrix of claim 1 wherein said matrix is custom-shaped to conform to said diseased, damaged, or defective cardiac tissue.

5. The [devitalized] matrix of claim 1 wherein said matrix comprises an injectable form of matrix.

6. The [devitalized] matrix of claim 1 wherein said matrix further comprises a pharmaceutical agent.

7. The [devitalized] matrix of claim 1 wherein said cardiac tissue is at least a portion of a cardiac valve.

8. The [devitalized] matrix of claim 1 wherein said matrix restores or replaces at least a portion of the interatrial septum.

9. The [devitalized] matrix of claim 1 wherein said cardiac tissue is at least a portion of the interventricular septum.

10. The [devitalized] matrix of claim 1 wherein said cardiac tissue is at least a portion of the myocardium.

11. A method for inducing restoration of [diseased or defective] cardiac tissue in a mammal, said method, comprising:

contacting a [devitalized] matrix comprising at least a portion of devitalized mammalian epithelial basement membrane and tunica propria subjacent to said basement membrane with diseased, defective, or [missing]damaged cardiac tissue, wherein said [devitalized] matrix induces restoration of [the diseased, defective, or missing said] cardiac tissue.

13. A composition, comprising:

at least a portion of devitalized epithelial basement membrane and tunica propria of a mucosa delaminated from [cells of] a mammalian epithelial tissue and shaped to conform to diseased, damaged, or defective cardiac tissue.

14. The composition of claim 13 further comprising submucosa[tunica propria delaminated from cells of a mammalian epithelium].

15. The composition of claim 14 further comprising muscle cells of the tunica muscularis[, delaminated from cells of a mammalian epithelial tissue].

18. The composition of claim 13 wherein said diseased, damaged, or defective cardiac tissue comprises at least a portion of a cardiac valve.

20. The composition of claim 13 wherein said diseased, damaged, or defective cardiac tissue comprises myocardium.